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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,900	02/23/2004	Nelson Scarborough	00167-492001 / 02-31-0466	5935
26170 7590 07/23/2007 FISH & RICHARDSON P.C. Smith & Nephew, Inc. 1450 Brooks Road Memphis, TN 38116			EXAMINER GILBERT, ANDREW M	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 07/23/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/782,900

Applicant(s)

SCARBOROUGH ET AL.

Examiner

Andrew M. Gilbert

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-15, 17, 18 and 38-68 is/are pending in the application.
- 4a) Of the above claim(s) 42, 43, 51 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-15, 17, 18 and 38-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/14/2007 has been entered.

### ***Acknowledgments***

2. This office action is in response to the reply filed on 5/14/2007.
3. In the reply, the Applicant added new claims 59-68 and cancelled claim 16. Claims 42-43, 51, 53 remain withdrawn.
4. Thus, claims 8-15, 17-18, 38-41, 44-50, 52, 54-68 are pending for examination.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 59 recites the limitation "response data indicative of magnitude and quality of a response". The limitation "magnitude and quality of a response" fails to particularly point out and distinctly claim the subject matter because the terms have no meaning in relation to the response. What defines the magnitude

and quality of a response of the patient? The interpretation of the limitation is subjective and unclear because a magnitude and quality of a response could literally be almost anything and could be defined in a subjective manner in a variety of ways.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 8-13, 41, 44-47, 52, 67-68 rejected under 35 U.S.C. 102(e) as being anticipated by Kraft (6370420).

9. In reference to independent claim 8, Kraft discloses a fluid introduction system, comprising: an introducer (14) configured to introduce fluid into a spine of a patient; an operator (18) configured to actuate the introducer to introduce fluid into the spine of the patient; a computer readable medium having code for receiving: fluid introduction data indicative of a fluid introduction parameter (col 3, lns 58-col 4, lns 13); and response data indicative (col 4, lns 13-col 37) of pain level and concordance of a response of the patient at a time related to a time of the fluid introduction data

10. In reference to claims 9-13, 41, 44-45 see (Summary, Figs 1-5; citations above and col 4, lns 66-col 6, lns 26).

11. In reference to independent claim 46, Kraft discloses a fluid introduction system, comprising: an introducer (14) configured to introduce fluid into a spine of a patient; an

operator (18) configured to actuate the introducer to introduce fluid into the spine of the patient; a computer readable medium having code for receiving: fluid introduction data indicative of a fluid introduction parameter (col 3, lns 58-col 4, lns 13); and response data indicative of a response of the patient manually inputted directly by the patient at a time related to a time of the fluid introduction data (col 4, lns 13-37; wherein the patient's vocalizations are a manual-patient conducted input).

12. In reference to claims 47, 52 see (22, col 3, lns 58-col 4, lns 2).

13. In reference to independent claim 67, Kraft discloses a fluid introduction system for performing discography diagnosis, comprising: an introducer (14) configured to introduce fluid into a spine of a patient; a computer readable medium having code for receiving: fluid introduction data indicative of a fluid introduction parameter (col 3, lns 58-col 4, lns 13); an pain level and concordance data of the patient responsive to the fluid introduction data (col 4, lns 13-37), wherein the discography diagnosis is based upon the correlation between the pain level and concordance data and the fluid introduction data (Summary, col 4, lns 66-col 6, lns 26).

14. In reference to independent claim 68, Kraft discloses a fluid introduction system for performing discography diagnosis, comprising: an introducer (14) configured to introduce fluid into a spine of a patient; a computer readable medium having code for receiving: fluid introduction data indicative of a fluid introduction parameter (col 3, lns 58-col 4, lns 13); and response data manually inputted directly by the patient (col 4, lns 13-37; wherein the patient's vocalizations are a manual-patient conducted input),

wherein the discography diagnosis is based upon the correlation between the response data and the fluid introduction data (Summary, col 4, lns 66-col 6, lns 26).

15. Claims 14-5, 17-18 and 55-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Hochman et al (6945954). Hochman et al discloses a fluid introduction system, comprising: an introducer (Fig 1) configured to introduce a non-pulsatile flow of fluid into a spine, the introducer having a flow rate-dependent impedance opposing the introduction of the fluid (Summary); and an operator (18) configured to actuate the introducer, the operator including code to determine impedance data indicative of the flow rate-dependent impedance based upon actuation of the introducer (col 3, lns 54-56; col 4, lns 2-5, 28-47; col 9, lns 28-48; col 10, lns 7-15; col 11, lns 41-62; col 12, lns 48-col 13, lns 16) and to control the actuation of the introducer based at least in part upon impedance data (col 3, lns 11-col 4, lns 54); wherein using the determined impedance data, the code corrects pressure data by the introduction of fluid and the pressure of fluid within the introducer (col 3, lns 54-56; col 4, lns 2-5, 28-47; col 9, lns 28-48; col 10, lns 7-15; col 11, lns 41-62; col 12, lns 48-col 13, lns 16); wherein the introducer includes an identifier (col 7, lns 10-13; 208) including the impedance data and the operator is configured to receive the impedance data from the identifier of the introducer; wherein the operator includes code to determine the impedance data based upon an actuation of the introducer (col 3, lns 11-col 4, lns 54; Program Listing); further comprising: a pressure sensor (7) configured to provide pressure data indicative of a pressure of fluid present in the introducer; a fluid introduction sensor (208)

configured to provide fluid introduction data indicative of at least one of (a) a rate of fluid introduction and (b) an amount of fluid introduced into the portion of the spine (col 3, Ins 11-col 4, Ins 54); wherein the operator includes code to determine the impedance data based upon the pressure data and the fluid introduction data (col 3, Ins 11-col 4, Ins 54, Program Listing); wherein the impedance data comprises a gauge of a fluid introduction member, a length of a fluid introduction member, an inner diameter of a fluid conduit; and a length of a fluid conduit (col 3, Ins 11-col 4, Ins 54; Program Listing; col 7, Ins 10-13; col 9, Ins 29-49).

### ***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 38-40, 48-50, 54, 59-61, 62-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraft in view of Factor et al (6258042). Kraft discloses the invention substantially as claimed except for expressly disclosing the response data being data inputted directly by the patient using a sliding device correlated to a visual analog scale (VAS) from 0-10 and has an axis for relating level of concordance, non-concordance, or concordance and non-concordance of the pain. Factor et al teaches that it is known to have a sliding device correlated to a visual analog scale with an axis for relating level of concordance, non-concordance, or concordance and non-

concordance of the pain (Fig 1-2, Summary; Detailed Description of Invention) for the purpose of allowing the patient to indicate the amount and intensity of pain being experienced in discrete incremental intervals. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the manually inputted response data as taught by Kraft with the manually inputted sliding VAS device as taught by Factor et al for the purpose of allowing the patient to indicate the amount and intensity of pain being experienced in discrete incremental intervals.

### ***Response to Arguments***

18. Applicant's arguments filed 5/14/2007 have been fully considered but they are not persuasive.

19. The Applicant argues that Hochman et al does not disclose or suggest determining impedance data indicative of the flow rate-impedance based upon an actuation of an introducer (Remarks, pg 11, paragraph 5 and pg 12, paragraph 3).

20. In response to the Applicant's argument, the Examiner respectfully disagrees and references the Applicant to (col 3, Ins 54-56; col 4, Ins 2-5, 28-47; col 9, Ins 28-48; col 10, Ins 7-15; col 11, Ins 41-62; col 12, Ins 48-col 13, Ins 16) of Hochman et al. In at least these sections of Hochman et al the device is described as determining impedance data, such as exit pressure, upon activation of the introducer and motion of the motor to introduce fluid into the target site. The motor is initiated and run at a predetermined rate consistent with the desired flow rate and the exit pressure is then monitored and changes in flow and pressure are made if undesirable exit pressures are found to occur. The rejection is maintained.



**Conclusion**

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 5653739; 4551133; 6159161.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

